Supreme Court, U.S.
FILED
SEP 13 2004
OFFICE OF THE CLERK

(10)

No. 03-932

IN THE

Supreme Court of the United States

DURA PHARMACEUTICALS, INC., *et al.*,

Petitioners,

v.

MICHAEL BROUDO, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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SEPTEMBER 13, 2004

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF THE *AMICUS CURIAE* 1

INTRODUCTION 2

BACKGROUND 3

A. The Life Sciences Industry 3

B. The Life Sciences Industry Is Fraught with Risk 6

C. The Life Sciences Industry Is a Breeding Ground for Securities Fraud Class Actions 9

D. Securities Fraud Class Actions Pose a Serious Threat to Life Sciences Companies 10

1. The Depletion of Capital 11

2. The Impact on Scientists and Researchers 12

3. The Distraction from Scientific Discovery 13

SUMMARY OF ARGUMENT 15

ARGUMENT 16

I. CONGRESS ESTABLISHED THE MOTION TO DISMISS STAGE IN A SECURITIES FRAUD CLASS ACTION AS A DEFINING POINT AT WHICH COURTS ARE TO ACT AS GATEKEEPERS 16

II. THE NINTH CIRCUIT'S DECISION WOULD IMPERMISSIBLY READ LOSS CAUSATION OUT OF RULE 10B-5 FRAUD-ON-THE-MARKET CLAIMS AND WOULD FRUSTRATE THE GATEKEEPING FUNCTION 21

A. The Ninth Circuit's Flawed Definition of Loss Causation Would Result in Windfall Damages and Render It Meaningless in Rule 10b-5 Fraud-on-the-Market Claims 21

B. A Rule 10b-5 Plaintiff Who Invokes the Fraud-on-the-Market Presumption Is Required to Plead a Corrective Disclosure 24

C. The Ninth Circuit's Decision Precludes Meaningful Review of Loss Causation at the Pleading Stage 25

III. THE NINTH CIRCUIT'S DECISION WOULD INCREASE THE RISK THAT MERITLESS CLASS ACTIONS WOULD BE PERMITTED TO PROCEED, WITH HARMFUL CONSEQUENCES TO THE LIFE SCIENCES INDUSTRY 26

CONCLUSION 29

TABLE OF AUTHORITIES

Page(s)

Cases:

Adler v. *Noven Pharm., Inc.*, No 03-22320 (S.D. Fla. filed Aug. 29, 2003) 13

Astoria Fed. Sav. & Loan Ass'n v. *Solimino*, 501 U.S. 104 1991) 23

Basic, Inc. v. *Levinson*, 485 U.S. 224 (1988) 15, 21, 22, 23, 24

Blue Chip Stamps v. *Manor Drug Stores*, 421 U.S. 723 (1975) 18

Central Bank of Denver, N.A. v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164 (1994) 18

City of Dearbern Heights Gen. Govt. Employees' Retirement Sys. v. *Vertex Pharm., Inc.*, No. 03-CV-11855 (D. Mass. filed Sept. 23, 2003) 13

Colandrea v. *IntraBiotics Pharm., Inc.*, No. 04-CV-2675 (N.D. Cal. filed July 2, 2004) 13

Emergent Capital Inv. Mgmt., LLC v. *Stonepath Group, Inc.*, 343 F.3d 189 (2d Cir. 2003) 19, 20

Ernst & Ernst v. *Hochfelder*, 425 U.S. 185, 201 (1976) 18

Greater Pa. Carpenters Pension Fund v. *Adolor Corp.*, No. 04-CV-1728 (E.D. Pa. filed Apr. 21, 2004) 13

Huddleston v. *Herman & MacLean*, 640 F.2d 534 (5th Cir. 1981) 20

Maitland v. Genta, Inc., No. 04-CV-2123 (D.N.J. filed May 4, 2004) 13

Paragamian v. *Vicuron Pharm., Inc.*, No. 04-CV-2627 (E.D. Pa. filed June 15, 2004) 13

Phillips v. *Regneron Pharm.*, No. 03-3111 (S.D.N.Y. filed May 2, 2003) 13

Price v. *Transkaryotic Therapies, Inc.*, No. 03-CV-10165 (D. Mass. filed Jan. 24, 2004) 13

Reiter v. *Sonotone Corp.*, 442 U.S. 330 (1979) 23

Robbins v. *Koger Props., Inc.*, 116 F.3d 1441 11th Cir. 1997) 19, 20, 23, 24

Semerenko v. *Cendant Corp.*, 223 F.3d 165 (3d Cir. 2000) 22. 24

Smith v. *Vaso Active Pharm., Inc.*, No. 04-CV-10708 (D. Mass. filed Apr. 8, 2004) 13

Whitkens v. *VaxGen, Inc.*, No. C-03-1129-JSW (N.D. Cal. filed Mar. 17, 2003) 14

Statutes, Rules, Regulations and Legislative History:

15 U.S.C. § 78u-4(b) 17

15 U.S.C. § 78u-4(b)(1)&(2) 19

15 U.S.C. § 78u-4(b)(3)(B) 18

15 U.S.C. § 78u-4(b)(4) 19

15 U.S.C. § 77l(b) 20

21 U.S.C. § 355(b) 8

21 C.F.R. § 312.21(a)(1)-(2) 7

21 C.F.R. § 312.21(b) 7

21 C.F.R. § 312.21(c) 8

21 C.F.R. § 314.50 8

Fed. R. Civ. P. 11(b) 17

Cong. Rec. S. 8850 (1997) 3

H.R. Conf. Rep. No. 104-369 (1995) 17, 19, 27

S. Rep. No. 104-98 (1995) 17, 18, 19, 26, 27, 28

Legal and Academic Journals:

Joseph A. DiMasi, et al. *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151 (2003) 11

Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH & ECON. 107 (1991) 8

Jonathan R. Macey et al., *Lessons from Financial Economics: Materiality, Reliance, and Extending the Reach of* Basic v. Levinson, 77 VA. L. REV. 1017 (1991) 22

Arti Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry*, 16 BERKELEY TECH. L.J. 813 (2001) 5

Ralph K. Winter, *Paying Lawyers, Empowering Prosecutors, and Protecting Managers: Raising the Cost of Capital in America*, 42 DUKE L.J. 945 (1993) 27

Symposium, *Financing the Biotech Industry: Can the Risks Be Reduced?*, 4 B.U. J. SCI. & TECH. L. 1 (1998) 8

Government and Industry Publications:

BIOTECHNOLOGY INDUSTRY ORGANIZATION, EDITORS' AND REPORTERS' GUIDE 2004-2005 ..... 3, 4, 11

CALIFORNIA HEALTHCARE INSTITUTE, BIOMEDICINE: THE NEW PILLAR IN NORTHERN CALIFORNIA'S ECONOMY (2002) 6

CENTER FOR DRUG EVALUATION RESEARCH, UNITED STATES FOOD & DRUG ADMINISTRATION, CDER HANDBOOK (1998) 7

CENTER FOR DRUG EVALUATION RESEARCH, UNITED STATES FOOD & DRUG ADMINISTRATION, FROM TEST TUBE TO PATIENT: IMPROVING HEALTH THROUGH HUMAN DRUGS (1999) 7, 8

CORNERSTONE RESEARCH, POST-REFORM ACT SECURITIES LAWSUITS, THE SETTLEMENTS REPORTED THROUGH DECEMBER 2003 12

DEPARTMENT OF COMMERCE, A SURVEY OF THE USE OF BIOTECHNOLOGY IN U.S. INDUSTRY (2003) 3, 4, 11

MICHAEL L. KICHLINE & DAVID A. KOTLER, DECHERT SURVEY OF SECURITIES FRAUD CLASS ACTIONS BROUGHT AGAINST LIFE SCIENCES COMPANIES (2004) 9, 10, 14

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2004 ..... 4, 8

PRICEWATERHOUSECOOPERS LLP, 2003 PRICEWATERHOUSECOOPERS SECURITIES LITIGATION STUDY (2004) 9

STANDARD & POOR'S INDUSTRY SURVEY: BIOTECHNOLOGY (2004) 4, 5, 6, 7, 12

STANDARD & POOR'S INDUSTRY SURVEYS, HEALTHCARE: PHARMACEUTICALS (2004) 4, 5, 6, 9

U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993) 5

VAXGEN, INC., FORM 10-K ANN. REP. PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DEC. 31, 2003 (2004) 14

Speeches:

Acting FDA Commissioner Lester M. Crawford, Remarks at Newsmaker Luncheon (Aug. 2, 2004) 2

Acting FDA Commissioner Lester M. Crawford, Remarks at Pharmaceutical Research and Manufacturers of America Annual Meeting (Apr. 3, 2004) 4

FDA Commissioner Mark B. McClellan, Remarks at Biotechnology Industry Organization Meeting (June 23, 2003) 2

Miscellaneous:

Julia Hannah, *The Business of Biotech, Between the Lab and the Boardroom, Biotech Companies Seek Success in a Future of Dizzying Possibilities*, HARV. BUS. SCH. BULLETIN, June 2004 ..... 6, 12

Bernadette Tansey, *Rise in Biotech Lawsuits Industry Blames Law Firms Looking for New Targets, But Some Investors Claim Companies Misled Them*, SAN FRAN. CHRONICLE, Jan. 26, 2004 9

Large Drug Mergers IMPACT Entire Pharmaceutical Chain, N.J. BUS., Feb. 1, 2003 28

On the Mend; Biotechnology, THE ECONOMIST, May 15, 2004 5

Internet Websites:

http://www.10b5.com 10

http://www.amgen.com 4

http://www.corixa.com 5, 6

http://www.medicis.com 5

http://www.pfizer.com 5

http://securities.stanford.edu 9, 12

http://www.vaxgen.com 14

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE*[1]

The Washington Legal Foundation ("WLF") is a national non-profit public interest law and policy center based in Washington, D.C., with supporters nationwide. WLF promotes legal reform in our civil justice system through publication on the topic by its Legal Studies Division. WLF also litigates cases and files *amicus curiae* briefs in this and other courts to oppose overreaching by courts that act contrary to the plain meaning of language chosen by Congress. WLF regularly opposes decisions that encourage the filing of abusive class actions in which the prospect of attorneys' fees being awarded to class action lawyers is paramount over the proper functioning of vital industries, such as the life sciences industry from which this case arises, the well-being of the nation's citizens and economy, absent class members, consumers and shareholders. The Ninth Circuit's decision is just such a decision.

For that reason, WLF will provide the Court with a broader public interest perspective in this case than that provided by the parties. WLF will focus on both the legal and policy reasons why the Ninth Circuit's decision, if permitted to stand, would threaten the life sciences industry, an industry that is vital to the well-being of our nation and its citizens.

[1] Letters from the parties consenting to the filing of this brief have been lodged with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for any party authored this brief, in whole or in part, and that no entity or person, aside from *amicus* and its counsel, made any monetary contribution to the preparation or submission of this brief.

INTRODUCTION

That Petitioner here is a life sciences company should not be surprising. Over recent years, securities class action lawyers have mounted an ever growing assault against the pharmaceutical and, particularly, biotechnology companies that make up the life sciences industry. The number of securities fraud class actions filed against life sciences companies has soared — from 2002 to 2003 these filings rose nearly 40%. And the percentage of overall securities fraud class actions that were filed against life sciences companies also soared — from 9% in 2002 to 15% in 2003. This is not mere chance. The life sciences industry is inherently risky and generates many more failed developmental efforts than successes, and at the announcement of such failures securities class action lawyers pounce.

This trend should be cause for serious alarm. Life sciences companies, as former FDA Commissioner Mark McClellan has said, "are not only achieving breakthroughs in the lab. They are making growing contributions to our economy, our homeland and national defense, and our public health — helping us live better lives than ever before."[2] The

[2] See FDA Commissioner Mark B. McClellan, Remarks before the Biotechnology Industry Organization (June 23, 2003), *available at* http://www.fda.gov/oc/speeches/2003/biotechnology0623.html. Acting FDA Commissioner Lester M. Crawford similarly said earlier this year that life sciences products — such as "biologics, drugs, foods, medical devices and veterinary medicines — are integral to public health as well as the fundamental economy upon which this great nation is based." Remarks at Newsmaker Luncheon (Aug. 2, 2004), *available at* http://www.fda.gov/oc/speeches/2004/newsmaker0802.html.

Congress also has acknowledged the vital importance of the industry. Most prominent among recent efforts to encourage life sciences companies to continue their important work is the passage of the Food and Drug Administration Modernization Act of 1997, at which time Congress recognized: "We are trying to take advantage of these marvelous technological breakthroughs in drugs and devices and products . . . and make

vital importance of the industry to our nation's well being is illustrated by the products being developed by life sciences companies that have been named in securities class actions. In the last year-and-a-half, class action lawyers have attacked companies attempting to develop products designed to treat cancer (Genta Inc.), pneumonia (Intrabiotics Pharmaceuticals, Inc.), skin disease (Vaso Active Pharmaceuticals, Inc.), infection (Vicuron Pharmaceuticals Incorporated), neurobehavioral problems in children (Noven Pharmaceuticals, Inc.), and HIV and hepatitis C (Vertex Pharmaceuticals Incorporated). Here, the Petitioner is being sued in connection with its attempt to develop a device to aid the treatment of asthma.

This brief focuses on the particular challenges that the life sciences industry faces from the threat posed by unrestrained filings of securities fraud class action lawsuits — a threat that will be exacerbated if the Ninth Circuit's decision in this case is not reversed.

BACKGROUND

A. The Life Sciences Industry.

The life sciences industry, broadly understood, comprise a wide array of complementary fields, the main ones of which are biotechnology and pharmaceuticals. Biotechnology is "the use of cellular and biomolecular processes to solve problems or make useful products."[3] In the field of

them available to American consumers to improve their health, to ensure their safety, to prolong their lives, to save their lives." Cong. Rec. S. 8850 (1997) (remarks of Sen. Coates, co-sponsor of the statute).

[3] BIOTECHNOLOGY INDUSTRY ORGANIZATION, EDITORS' AND REPORTERS' GUIDE 2004-2005 1 [hereinafter BIO GUIDE] available at http://www.bio.org/speeches/pubs; see also DEPARTMENT OF COMMERCE, A SURVEY OF THE USE OF BIOTECHNOLOGY IN U.S. INDUSTRY 3 (2003) [hereinafter COMMERCE BIOTECH SURVEY], available at

human health, to give a few examples, biotechnology companies produce medical diagnostic devices, such as gene probes, DNA markers, and new types of blood tests.[4] They also produce drugs and other therapeutics, such as vaccines, and "regenerative medicine" products, such as new proteins and antibodies.[5] Pharmaceutical companies make drugs to improve human health and treat an immense range of physical and mental illnesses.[6]

Both biotechnology and pharmaceutical companies run the gamut in size, from giants such as Amgen Inc. and Pfizer Inc. to small firms such as Corixa Corporation and Medicis Pharmaceutical Corporation.[7] Larger life sciences compa-

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http://www.usinfo.state.gov/usa/infousa/tech/biotech.html; STANDARD & POOR'S INDUSTRY SURVEY: BIOTECHNOLOGY 12 (2004) [hereinafter S&P BIOTECH SURVEY].

[4] COMMERCE BIOTECH SURVEY 26; BIO GUIDE 37-38; see also Acting FDA Commissioner Lester M. Crawford, Remarks at Pharmaceutical Research and Manufacturers of America Annual Meeting (Apr. 3, 2004) (discussing new medical advances), *available at* http://www.fda.gov/oc/speeches/2004/phrma0403.html.

[5] COMMERCE BIOTECH SURVEY 26; BIO GUIDE 38-44.

[6] STANDARD & POOR'S INDUSTRY SURVEYS, HEALTHCARE: PHARMACEUTICALS 11-15 (2004) [hereinafter S&P PHARMACEUTICALS SURVEY] (discussing drugs aimed at treating, among other diseases, depression, multiple sclerosis, and diabetes); see also PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2004, at 10-16 [hereinafter PHRMA PROFILE] (discussing new drugs for treating AIDS and Alzheimer's), *available at* http://www.phrma.org/publications.

[7] Amgen is the world's largest biotechnology company, with more than $5 billion in revenue in 2003 and nearly 13,000 employees; among other things, Amgen uses cellular biology to treat cancer. See http://www.amgen.com; S&P BIOTECH SURVEY 1-5, 7-9 (discussing Amgen drugs and its financial performance). Pfizer is the world's largest pharmaceutical company, number 25 in the Fortune 500, with more than $45 billion in revenue in 2003 and 122,000 employees worldwide; its best known products include Zoloft, for depression, and Lipitor, for high cholesterol.

nies have been turning more and more to smaller biotechnology firms to supplement in-house research and development efforts.[8] In particular, the smaller biotechnology firms are performing much of the important research and development in the industry today.[9] Once a small company identifies a promising prospect, a large company can provide it with

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See http://www.pfizer.com/are/mn_about_company.html; see also S&P PHARMACEUTICALS SURVEY 7-15 (discussing some of Pfizer's drugs), 7, 34-38 (financial performance).

Other companies are much smaller, though no less key. Corixa, for example, had about $13 million in revenue for the first half of 2004 and employs 380 people. It uses biotechnology in immunotherapy and has one drug currently on the market. See http://www.corixa.com. Medicis, which specializes in dermatological drugs, had $88 million in revenue for its most recent fiscal year and employs 300. See http:// www.medicis.com.

[8] See generally Arti Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry*, 16 BERKELEY TECH. L.J. 813, 814-20 (2001) (discussing the numerous "strategic alliances" between biotech and pharmaceutical firms).

[9] See, *e.g.*, S&P PHARMACEUTICALS SURVEY 3, 25 (noting that "[m]ajor pharmaceutical companies are redoubling their efforts in developing new products by forming marketing and development alliances with . . . smaller biotechnology companies."); S&P BIOTECH SURVEY 16 ("New collaborative agreements have risen steadily in recent years, as Big Parma (large-capitalization pharmaceutical firms) and major biotechs have come to realize the scientific and economic benefits of partnerships with smaller biotech firms."); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 10 n.9 (1993) (noting that smaller biotechnology companies seek financial funding from pharmaceutical companies when other funding sources are not available), 1131 (describing pharmaceutical companies multi-tiered approach to research and development, which includes collaborations with specialized biotechnology companies, in addition to in-house research); see also *On the Mend; Biotechnology*, THE ECONOMIST, May 15, 2004, at 60 ("[Biotechnology companies'] productivity is reflected in lucrative deals with big drugmakers which are struggling to fill their own sluggish R&D pipelines.").

money for research and development and other costs, as well as an experienced sales force and production facilities.[10]

B. The Life Sciences Industry Is Fraught with Risk.

The life sciences industry is characterized by an extraordinarily high level of risk. The industry is predicated upon science — a constantly evolving process of exploration, experimentation, and discovery. By its very nature, science often produces incomplete, inconsistent, or unexpected results. As a result, the discovery of useful, marketable compounds is rare. Tellingly, only one of every 5,000 discovered compounds ultimately becomes a marketable drug.[11]

And life sciences companies seeking approval of their products must complete the rigorous clinical trial process

[10] See S&P BIOTECH SURVEY 8, 15-16; S&P PHARMACEUTICALS SURVEY 3, 25. In 2003, these partnership deals totaled nearly $10 billion. *Id.* at 16. Corixa is illustrative. It has reached agreements with over a dozen large drugmakers, and developed its one drug now on the market in a partnership with GlaxoSmithKline. See http://www.corixa.com.

[11] S&P PHARMACEUTICALS SURVEY 18 ("Financially, drug-manufacturing is a high-risk business"); Julia Hannah, *The Business of Biotech, Between the Lab and the Boardroom, Biotech Companies Seek Success in a Future of Dizzying Possibilities*, HARV. BUS. SCH. BULLETIN, June 2004 ("In biotech, one big drug will make you very profitable for a long time, but the percentage of drugs that make it to market is so low that it remains a risky proposition.") (quoting Professor Gary P. Pisano), *available at* http://www.alumni.hbs.edu/bulletin/2000/june/biotech.html; CALIFORNIA HEALTHCARE INSTITUTE, BIOMEDICINE: THE NEW PILLAR IN NORTHERN CALIFORNIA'S ECONOMY 14 (2002) ("But because scientific discovery and medical innovation require experimentation, and each step in bringing new products to market is tightly regulated by the government, biotechnology R&D in Northern California, as elsewhere, is a risky, lengthy and costly business."), *available at* http://www.pwc.com/technology/lifesciences/CA%20Biomed%20R&D %20 Survey%202002_NORTHERN%20 CAL.pdf.

required by the Food and Drug Administration ("FDA"). The process takes years to complete and comes with a high likelihood of failure. And it begins only after years of expensive and time-consuming laboratory and animal preclinical testing.[12] At each stage of the clinical trial process, failure or negative results are likely.

The FDA-regulated clinical trial process generally has three phases. Phase I involves the preliminary testing of a new product on humans.[13] Only approximately 70 out of every 100 drugs beginning human clinical trials complete Phase I.[14] Where results indicate that further study is safe, Phase II testing can proceed. Phase II clinical trials involve months or even years of safety and efficacy testing.[15] If Phase II data indicates that the product is safe and that it provides "preliminary evidence suggesting effectiveness of the drug,"[16] the FDA will authorize a comprehensive Phase III clinical trial.[17] Only 33 out of every 100 drugs tested on humans complete Phase II.[18]

[12] See generally S&P BIOTECH SURVEY 18-20 (summarizing regulatory process).

[13] See 21 C.F.R. § 312.21(a)(1)-(2). See generally CENTER FOR DRUG EVALUATION RESEARCH, UNITED STATES FOOD & DRUG ADMINISTRATION, CDER HANDBOOK 8 (1998) [hereinafter CDER HANDBOOK].

[14] See CENTER FOR DRUG EVALUATION RESEARCH, UNITED STATES FOOD & DRUG ADMINISTRATION, FROM TEST TUBE TO PATIENT: IMPROVING HEALTH THROUGH HUMAN DRUGS 22 (1999) [hereinafter TEST TUBE TO PATIENT], *available at* http://www.fda.gov/fdac/special/newdrug/ndd_toc.html.

[15] See 21 C.F.R. § 312.21(b).

[16] See *id.*

[17] See CDER HANDBOOK 10.

[18] See TEST TUBE TO PATIENT 21.

Phase III clinical trials are an even more significant undertaking; they often involve years of safety, efficacy, and dosage testing on hundreds and often thousands of patients.[19] The costs associated with Phase III clinical studies are staggering, running well into the million of dollars per drug.[20] And only 20-25% of drugs that begin human testing complete Phase III.[21] At the conclusion of a successful Phase III study, the sponsoring drug company still must submit a New Drug Application to the FDA.[22] In the end, only 20% of the products that begin the FDA clinical process in Phase I ultimately receive FDA approval.[23]

Even if a life sciences company gains FDA approval for a candidate, it faces further risks and uncertainties in commercializing the product. Companies wholly dedicated to developing a product must shift focus to concentrate on production, marketing, and distribution. Smaller companies often do not have these capabilities, so they must enter into partnering agreements with larger companies. The product manufacturing process is highly regulated and regimented. The manner in which a drug is advertised and marketed is also highly regulated. Each of these difficult steps involves some degree of risk of failure and reduces the likelihood that a drug will ever be a commercial success. Indeed, only one out of three drugs approved by the FDA generates a financial

[19] See 21 C.F.R. § 312.21(c).

[20] See Symposium, *Financing the Biotech Industry: Can the Risks Be Reduced?*, 4 B.U. J. Sci. & Tech. L. 1, 86 n.208 (1998) (noting that Phase III trials can cost from $1 million to $20 million).

[21] See TEST TUBE TO PATIENT 21.

[22] See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50.

[23] See TEST TUBE TO PATIENT 35; see also http://www.fda.gov/fdac/special//newdrug/testtabl.html; PHRMA PROFILE 2-3; Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH & ECON. 107, 124 (1991).

return sufficient to cover the costs of its own research and development.[24]

C. The Life Sciences Industry Is a Breeding Ground for Securities Fraud Class Actions.

Because the product life cycle is fraught with risk of failure or negative results, publicly-traded life sciences companies face great potential for adverse market events. When a company, particularly a smaller one, makes a negative announcement, the market typically reacts, the stock price declines, and the class action bar swings into action. No matter the cause of the market event, the response is usually a deluge of securities fraud class actions asserting boilerplate allegations that the company "fraudulently concealed" whatever facts led to the stock price decline, and that the "truth" was only later revealed with the bad news. The life sciences industry is facing a litigation crisis — a "growing, malignant phenomenon" that is hampering the discovery of life-saving remedies.[25]

The numbers bear this out. In 2003, securities fraud actions against life sciences companies increased by 39% from 2002.[26] And the number of securities class actions brought

[24] S&P PHARMACEUTICAL SURVEY 18.

[25] Bernadette Tansey, *Rise in Biotech Lawsuits, Industry Blames Law Firms Looking for New Targets, But Some Investors Claim Companies Misled Them*, SAN FRAN. CHRONICLE, Jan. 26, 2004, at E1 (quoting Carl Feldbaum, President of Biotechnology Industry Organization).

[26] See MICHAEL L. KICHLINE & DAVID A. KOTLER, DECHERT SURVEY OF SECURITIES FRAUD CLASS ACTIONS BROUGHT AGAINST LIFE SCIENCES COMPANIES 3 (2004) [hereinafter CLASS ACTION SURVEY], *available at* http://www.dechert.com/eventspubs/eventspubs.jsp?pg=lawyer_pubications_detail&id=4477. The underlying numbers for the survey are derived from the listing of class action complaint filings posted on the Stanford Clearinghouse website, *available at* http://securities.stan-ford.edu; see also PRICEWATERHOUSECOOPERS LLP, 2003 PRICEWATERHOUSECOOP-

against life sciences companies also increased as a percentage of overall securities fraud class actions. While life sciences companies were defendants in only 9% of all securities fraud class actions in 2002, that number rose to 15% in 2003.[27] *All* of the class actions filed in 2003 and 2004 against life sciences companies involve fraud-on-the-market claims.

The filings against life sciences companies are alarming not only in number, but in breadth of subject matter as well. These lawsuits typically allege misrepresentations and/or non-disclosures regarding product efficacy, product safety, clinical trial results, the FDA approval process, the quality of manufacturing processes, commercial alliances, marketing and advertising activities, and faulty accounting and/or finances.[28] Virtually every aspect of the business — from development to production to marketing to commercialization — is under attack.

D. Securities Fraud Class Actions Pose a Serious Threat to Life Sciences Companies.

The rising number of securities fraud class actions poses grave risks to the industry and, accordingly, the nation. While it is inevitable that companies in the industry will face litigation, including securities litigation, the industry cannot afford to divert its already limited and strained resources to defend baseless lawsuits. For this reason, ensuring that meritless complaints are dismissed at the pleading stage is critically important.

ERS SECURITIES LITIGATION STUDY 5 (2004) (noting that one "emerging trend" is "securities litigation against pharmaceutical companies"), *available at* http://www.10b5.com.

[27] CLASS ACTION SURVEY 3.

[28] *Id.* at 4-6.

1. The Depletion of Capital.

The life sciences industry is capital intensive. Biotechnology segments of companies spend more capital as a percentage of net sales than do non-biotechnology segments, and capital expenditures are higher per employee.[29] Research and development costs are also high. Biotechnology firms spend more as a percentage of total research and development expenditures in the United States than do the aerospace, machinery, or chemical industries.[30] In 2002 alone, biotechnology companies spent more than $20 billion on research and development.[31] Research and development "intensity" — the ratio of research and development spending to net sales — was eight times higher for biotechnology companies than the average U.S. business.[32] In the pharmaceutical world, capital is just as critical. Developing a new drug costs more than $800 million on average — and capital costs have increased in recent years 7% faster than inflation.[33]

The industry's critical reliance on capital, particularly with regard to the smaller developmental stage companies that generate little to no revenue, is one reason that the increase of securities fraud class actions filed against life sciences companies is so dangerous. These suits sap capital. The cost of defending a securities class action lawsuit is substantial, and a recent survey reports that the median

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[29] COMMERCE BIOTECH SURVEY 72.

[30] *Id.* at 73.

[31] BIO GUIDE 3.

[32] COMMERCE BIOTECH SURVEY 73.

[33] Joseph A. DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151, 166-68 (2003).

settlement amount is over $6 million while the average is approximately $20 million.[34]

2. The Impact on Scientists and Researchers.

The life sciences industry relies on uniquely qualified scientists, doctors, and researchers. The research and development process for new life sciences products is, by its nature, cutting-edge work, and correspondingly requires highly talented and skilled people. These individuals also must be "insightful and quick-thinking individuals," with the skills to manage.[35] They must not only be at the top of their area of science or medicine but also possess the knowledge and experience to successfully develop and commercialize a product, to manage research teams, and to handle ever more complex regulatory relationships.[36]

In a foreboding new trend, however, the securities fraud complaints against life sciences companies have gone beyond naming chief executives or other high ranking business people, the traditional defendants in securities fraud cases. Class action lawyers are now suing some of the most critical members of the industry's workforce — the scientists, researchers, and medical personnel that manage much of the industry's vital research and development.[37]

[34] Cornerstone Research, POST-REFORM ACT SECURITIES LAWSUITS, THE SETTLEMENTS REPORTED THROUGH DECEMBER 2003 2, *available at* securities.stanford.edu/Settlements/REVIEW_1995-2003/2003_Settlements _Release.pdf.

[35] S&P BIOTECHNOLOGY SURVEY 24; Julia Hannah, *The Business of Biotech, Between the Lab and the Boardroom, Biotech Companies Seek Success in a Future of Dizzying Possibilities*, HARV. BUS. SCH. BULLETIN, June 2002 ("'Once you attract bright, young scientists . . . you need to get them to realize this is not a postdoc lab, this is a business. It's not enough just to do the experiment; somebody's got to take the ball and run with it.'") (quoting Professor Gary P. Pisano of the Harvard Business School).

[36] S&P BIOTECH SURVEY 24-25.

3. The Distraction from Scientific Discovery.

Financial capital and human talent are only two of the key ingredients to the success of a life sciences company. The company must focus these resources on the scientific exploration needed to yield life-saving or life-enhancing products. This process can produce successful results only if it is supported and driven by an institutional, company-wide focus on achieving the company's core developmental objectives.

This is particularly so with the smaller biotechnology companies. In 2003, nearly half of the life sciences defen-

[37] See, *e.g.*, *Colandrea* v. *IntraBiotics Pharm., Inc.*, No. 04-CV-2675 (N.D. Cal. filed July 2, 2004) (naming "Senior Vice President of Pre-Clinical and Clinical Research and Development and Chief Medical Officer"); *Greater Pa. Carpenters Pension Fund* v. *Adolor Corp.*, No. 04-CV-1728 (E.D. Pa. filed Apr. 21, 2004) (naming "Vice President, Clinical Research and Development" and "Senior Vice-President, Research and Development"); *Maitland* v. *Genta, Inc.*, No. 04-CV-2123 (D.N.J. filed May 4, 2004) (naming "President, Pharmaceutical Development and Chief Medical Officer"); *Paragamian* v. *Vicuron Pharm., Inc.*, No. 04-CV-2627 (E.D. Pa. filed June 15, 2004) (naming "Chief Medical Officer"); *Smith* v. *Vaso Active Pharm., Inc.*, No. 04-CV-10708 (D. Mass. filed Apr. 8, 2004) (naming "Chief Scientific Officer"); *Adler* v. *Noven Pharm., Inc.*, No 03-22320 (S.D. Fla. filed Aug. 29, 2003) (naming "Chief Technical Officer"); *City of Dearborn Heights Gen. Govt. Employees' Retirement Sys.* v. *Vertex Pharm., Inc.*, No. 03-CV-11855 (D. Mass. filed Sept. 23, 2003) (naming "Chief Technology Officer" and "Senior Vice President, Drug Evaluation and Approval"); *Phillips* v. *Regneron Pharm.*, No. 03-3111 (S.D.N.Y. filed May 2, 2003) (naming "Chief Scientific Officer" and "Vice-President of Clinical Studies"); *Price* v. *Transkaryotic Therapies, Inc.*, No. 03-CV-10165 (D. Mass. filed Jan. 24, 2004) (naming "Chief Scientific Officer and Chairman of the Scientific Advisory Board"). These complaints can be viewed at http://securities.stanford.edu/companies.html.

dants had market capitalizations of less than $500 million.[38] And more than twenty percent had market capitalizations of less than $100 million.[39] Many of these companies generate little revenue and focus on developing only one or two products. Their staffing is lean, averaging fewer than 320 employees, with several companies having fewer than 200 or even 100 employees.

For instance: one of the smaller biotechs that has been sued is VaxGen, Inc. VaxGen has a current market capitalization of approximately $260 million and only 133 employees.[40] Its initial focus was on developing a vaccine for HIV. When the company announced apparently disappointing Phase III clinical trial results, it was sued in several securities fraud class actions.[41] VaxGen has since shifted its priorities away from the HIV vaccine to the development of other vaccines (to combat bioterrorism)[42] but remains saddled with the cost and distraction of the class actions. As VaxGen was forced to warn investors in its SEC filings: "These lawsuits could also result in continued diversion of our time and attention away from business operations, which could harm our business."[43]

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[38] CLASS ACTION SURVEY 3.

[39] *Id.*

[40] VAXGEN, INC., FORM 10-K ANN. REP. PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DEC. 31, 2003, 15 [hereinafter VAXGEN ANNUAL REPORT] (2004), *available at* http://ir.10kwizard.com/contents.php?ipage=2701872&repo=tenk&source=873.

[41] See *Whitkens* v. *VaxGen, Inc.*, No. C-03-1129-JSW (N.D. Cal. filed Mar. 17, 2003).

[42] See generally http://www.vaxgen.com.

[43] VAXGEN ANNUAL REPORT 27.

SUMMARY OF ARGUMENT

The Private Securities Litigation Reform Act of 1995 ("Reform Act") was Congress's response to, among other abuses, class action lawyers' maneuver of seizing upon the expense and disruption of discovery to exact unwarranted settlements. Congress's answer to this abusive tactic was to appoint the district courts as gatekeepers to the discovery process. Congress thus required courts to stay discovery once a defendant moved to dismiss a securities fraud class action complaint. Congress also heightened and supplemented the standards for pleading a securities fraud claim. This included the statutory codification of "loss causation" as an element of a Rule 10b-5 claim. Loss causation requires plaintiffs to plead and prove that their loss was directly caused by the misrepresentation, not simply that the plaintiffs entered into the challenged transaction because of the misrepresentation (transaction causation).

The Ninth Circuit's decision reads loss causation out of the Reform Act and, as a consequence, contravenes the Congressional mandate that the district courts serve as gatekeepers. The Ninth Circuit required that the plaintiff allege only that the misrepresentation artificially inflated the stock price at the time of purchase and expressly rejected the need to allege that a corrective disclosure later removed the artificial price inflation. That decision not only is wholly inconsistent with the words and intent of the Reform Act, but it also invites potential windfall damages awards for plaintiffs who sell or continue to hold the security before the artificial inflation is removed. It also improperly extends the presumption under the fraud-on-the-market theory, which this Court limited to reliance in *Basic, Inc.* v. *Levinson*, 485 U.S. 224 (1988), to loss causation.

The correct — indeed, Congressionally mandated — pleading standard for loss causation on a Rule 10b-5 claim is

this: A plaintiff must allege a corrective disclosure — that is, an announcement or other action that revealed the misrepresentation, thereby causing the efficient market to remove the artificial price inflation. This rule, not the Ninth Circuit's holding, is faithful to Congress's decision to establish "loss causation" as an element of a Rule 10b-5 claim. It requires that the misrepresentation be directly linked to an actual loss for which the plaintiff can recover. This test comports with the Reform Act and this Court's decision in *Basic*.

And, of particular importance to a life sciences company such as Petitioner, reversing the Ninth Circuit's decision will ensure that meritless suits are properly dismissed at the pleading stage. The life sciences industry seeks to develop products vital to everyday existence. It is a capital intensive industry, always struggling to raise capital and find the rare, highly skilled people who can conduct its research and development. The availability of capital, its cost, and the availability of qualified personnel cannot be left to the whims and profit motives of class action lawyers looking to exact undeserved settlements.

ARGUMENT

I. CONGRESS ESTABLISHED THE MOTION TO DISMISS STAGE IN A SECURITIES FRAUD CLASS ACTION AS A DEFINING POINT AT WHICH COURTS ARE TO ACT AS GATEKEEPERS.

Congress enacted the Reform Act to remedy wide-ranging abuses of the securities fraud class action process. The Reform Act contained sweeping remedies for those abuses, including heightened and supplemented pleading standards, a required stay of discovery pending a motion to dismiss, a requirement that lead plaintiffs, not just lawyers, have a strong financial interest in the litigation, and a required review of the plaintiffs' lawyers' compliance with

their obligations under Fed. R. Civ. P. 11(b). See 15 U.S.C. § 78u-4(b).

Foremost among Congress's concerns were abuses of the discovery process to force defendants into settlements.[44] As the Senate Committee on Banking, Housing and Urban Affairs put it, the "cost of discovery often forces defendants to settle abusive securities class actions. . . . In addition, the threat that the time of key employees will be spent responding to discovery requests, such as providing deposition testimony, may force coercive settlements."[45] Congress was particularly concerned that these securities class actions were settling for reasons other than the merits:

> The settlement value to defendants turns more on the expected costs of defense than the merits of the underlying claim. . . . If a defendant cannot win an early dismissal of the case, the economics of litigation may dictate a settlement even if the defendant is relatively confident that it would prevail at trial.[46]

This Court has expressed the same concerns regarding securities "strike suits," particularly with regard to discovery abuses:

> [T]o the extent that it permits a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the

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[44] See H.R. Conf. Rep. No. 104-369, at 31 (1995) (citing abuse of the "discovery process to impose costs so burdensome that it is often economical for the victimized party to settle").

[45] S. Rep. No. 104-98, at 14 (1995).

[46] *Id.* at 6-7; see also H.R. Conf. Rep. No. 104-369, at 37 ("The cost of discovery often forces innocent parties to settle frivolous securities class actions.").

> right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonable founded hope that the process will reveal relevant evidence, it is a social cost rather than a benefit.

Blue Chip Stamps v. *Manor Drug Stores*, 421 U.S. 723, 741 (1975); see also *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 189 (1994) (recognizing "danger of vexatiousness different in degree and in kind from that which accompanies litigation in general").

To curb the coercive effect of these discovery abuses, Congress established the motion to dismiss as a defining point in securities fraud class action litigation. It accomplished this in two ways.

First, it appointed the federal courts as gatekeepers to the discovery process, requiring courts to stay "all discovery" in a securities class action pending a defendant's motion to dismiss the complaint. See 15 U.S.C. § 78u-4(b)(3)(B). With this, Congress ensured that class action lawyers could not wield the expense and disruption of discovery as a weapon to coerce a settlement without first having shown that they filed a legally sufficient complaint.[47]

Second, in the same subsection in which it required courts to stay discovery, the Reform Act supplemented and heightened the pleading requirements to be enforced on a motion to dismiss. It did so by requiring securities fraud plaintiffs to plead facts "giving rise to a strong inference" of scienter, a longstanding element of a Rule 10b-5 claim, *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 201 (1976), and by

[47] S. Rep. No. 104-98, at 4, 14 ("discovery should be permitted in securities class actions only after the court has sustained the legal sufficiency of the complaint").

requiring plaintiffs to plead any alleged misstatements or omissions with specificity, including the reasons why they were misleading. See 15 U.S.C. § 78u-4(b)(1) & (2).

Congress also supplemented the pleading requirements, again in that same subsection, by requiring securities plaintiffs to plead and prove loss causation: "Loss causation. — In any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). The report from the managers of the House and Senate made clear that plaintiffs must "plead" this element.[48] The Senate Committee further confirmed that this was an added pleading requirement, as its report discussed the addition of loss causation in the section entitled "A strong pleading requirement."[49]

Loss causation is peculiar to Rule 10b-5 litigation. It provides that a plaintiff can recover only if the alleged economic loss is directly linked to the falsity of the alleged misrepresentation. See *Emergent Capital Inv. Mgmt., LLC* v. *Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003) (holding that loss causation is the connection "between the alleged misconduct and the economic harm ultimately suffered by the plaintiff."); *Robbins* v. *Koger Props., Inc.*, 116 F.3d 1441, 1447 (11th Cir. 1997) ("[L]oss causation describes the link between the defendant's misconduct and the plaintiff's economic loss."). The Senate Committee explained that loss causation requires plaintiffs to show "that the loss in the value of their stock was caused by the Section 10(b) violation and not other factors."[50] This comports with

[48] See H.R. Conf. Rep. No. 104-369, at 41.

[49] S. Rep. No. 104-98, at 15.

[50] *Id.* at 7.

the definition used in a related section of the Reform Act, which established loss causation as an element of a claim under the Securities Act of 1933, stating that it restricts recoverable damages to only those that result from the falsity of the misstatement, and not from other factors. See 15 U.S.C. § 77l(b).

A related, though different, element in a Rule 10b-5 claim is "transaction causation." Transaction causation is akin to "but for" causation in the common law. It requires that the plaintiff show that he or she would not have entered into the challenged transaction "but for" the defendant's fraud. *Emergent*, 343 F.3d at 197 ("[Transaction causation] is established simply by showing that, but for the claimed misrepresentations or omissions, the plaintiff would not have entered into the detrimental securities transaction."). Courts have often used "transaction causation" and "reliance" interchangeably. See *id.* ("Like reliance, transaction causation refers to the causal link between the defendant's misconduct and the plaintiff's decision to buy or sell securities."); *Robbins*, 116 F.3d at 1447 ("Transaction causation, another way of describing reliance, is established when the misrepresentation or omissions cause the plaintiff to engage in the transaction in question.") (internal quotations omitted); *Huddleston* v. *Herman & MacLean*, 640 F.2d 534, 549 (5th Cir. 1981) (treating the reliance element of a Rule 10b-5 claim as transaction causation).

The Congressionally mandated element of loss causation plays an important role in determining whether a plaintiff is seeking the type of damages authorized by Congress. As discussed below, the Ninth Circuit's decision improperly abandons this requirement.

II. THE NINTH CIRCUIT'S DECISION WOULD IMPERMISSIBLY READ LOSS CAUSATION OUT OF RULE 10B-5 FRAUD-ON-THE-MARKET CLAIMS AND WOULD FRUSTRATE THE GATEKEEPING FUNCTION.

The Ninth Circuit's decision runs counter to what Congress sought to achieve by passing the Reform Act. It creates a definition of loss causation that is little more than "transaction causation" (or reliance), and then presumes it away under the fraud-on the-market theory. But by not requiring plaintiffs who invoke the fraud-on-the-market theory to plead a corrective disclosure — that is, a disclosure that removed the artificial inflation in the security's market price — the Ninth Circuit improperly relieves plaintiffs of the Congressionally mandated requirement to plead a direct causal link between the falsity of the misrepresentation and the loss.

A. The Ninth Circuit's Flawed Definition of Loss Causation Would Result in Windfall Damages and Render It Meaningless in Rule 10b-5 Fraud-on-the-Market Claims.

The Ninth Circuit's definition of loss causation requires only that a plaintiff plead that the security's "price at the time of the purchase was overstated." Pet. App. at 9a. In other words, it focuses solely on inflation of the market price at the time that the plaintiff purchased the security rather than any loss that the plaintiff may have suffered once that artificial inflation was removed.

In a fraud-on-the-market case, where a plaintiff is invoking and relying upon an efficient market, this definition's fundamental flaw is that the artificial price inflation must actually be removed before a plaintiff can suffer a compensable loss. The very presumption that underlies the fraud-on-the-market theory is that the security trades on an efficient market. *Basic*, 485 U.S. at 246 ("Recent empirical

studies have tended to confirm Congress' premise that the market price of shares traded on well-developed markets reflects all publicly available information, and, hence, any material misrepresentations."); *Semerenko* v. *Cendant Corp.*, 223 F.3d 165, 178 (3d Cir. 2000) (noting that "[u]nder the fraud on the market theory of reliance, the court presumes . . . that the market price of the security actually incorporated the allege misrepresentations"). Thus, if a corrective disclosure has not been made, the market price will continue to hold the artificial inflation. Plaintiffs who still hold the stock can simply resell the stock and recoup the artificial inflation that they initially overpaid. And plaintiffs who have already sold their stock have already recouped the artificial inflation. Awarding any of these plaintiffs damages would provide them with an undeserved windfall.

The practical effect of the Ninth Circuit's definition is to render loss causation meaningless in fraud-on-the-market cases. In *Basic*, this Court approved the fraud-on-the-market theory. 485 U.S. at 241-48. It authorized the use of the efficient market hypothesis to presume that a plaintiff, rather than relying on a specific material misrepresentation, relied on the efficient market to incorporate all material information, including the misrepresentation, into the market price. *Id.* This removed the barrier that individual reliance issues had posed to Rule 10b-5 class actions and allowed plaintiffs' lawyers to bring large class actions.[51] *Id.* at 242.

But the *Basic* decision authorized the presumption of reliance, and no more. It explicitly framed the question before it as "whether it was proper for the courts below to apply a

[51] Jonathan R. Macey et al., *Lessons from Financial Economics: Materiality, Reliance, and Extending the Reach of* Basic v. Levinson, 77 VA. L. REV. 1017, 1020 n.9 (1991) (noting that "the traditional reliance requirement [wa]s a particularly difficult hurdle for plaintiffs in class action law suits" before *Basic*).

rebuttable presumption of *reliance*, supported in part by the fraud-on-the-market theory." *Id.* (emphasis added). It then determined that, "[b]ecause most publicly available information is reflected in market price, an investor's *reliance* on any public material misrepresentations, therefore, *may be presumed* for purposes of a Rule 10b-5 action." *Id.* at 247 (emphasis added). *Basic* made no mention of presuming any other element of a Rule 10b-5 claim. See *Robbins*, 116 F.3d at 1448 ("But the fraud on the market theory, as articulated by the Supreme Court, is used to support a rebuttable presumption of reliance, not a presumption of causation.").

The Ninth Circuit's decision, however, improperly extends the *Basic* presumption to loss causation. A Rule 10b-5 fraud-on-the-market plaintiff would be required to plead no more than the elements that it was required to plead before Congress passed the Reform Act. A Rule 10b-5 plaintiff following the Ninth Circuit's definition would need to plead only a material misrepresentation, a longstanding element of a Rule 10b-5 claim, and the efficient market would then be presumed to incorporate that material misrepresentation into the security's price, thereby artificially inflating it. *Basic*, 485 U.S. at 246. Since this artificial inflation satisfies the Ninth Circuit's definition of loss causation, the efficient market theory would therefore presume not only reliance (or transaction causation), but also loss causation.

Not only does this extend *Basic* well beyond its own plain terms, it renders meaningless Congress's decision to codify loss causation as a distinct element of a Rule 10b-5 claim. Under a basic canon of statutory construction courts may not interpret a statutory provision so as to render any part meaningless or superfluous. *E.g.*, *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 112 (1991) ("[W]e construe statutes, where possible, so as to avoid rendering superfluous any parts thereof."); *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 339 (1979) ("In construing a statute we are

obliged to give effect, if possible, to every word Congress used.").

B. A Rule 10b-5 Plaintiff Who Invokes the Fraud-on-the-Market Presumption Is Required to Plead a Corrective Disclosure.

To plead loss causation in a fraud-on-the-market case, a plaintiff is required to plead that a corrective disclosure or disclosures removed the artificial inflation from the market price of the security and thereby caused an economic loss. See *Semerenko*, 223 F.3d at 185 ("In the absence of a correction in the market price, the cost of the alleged misrepresentation is still incorporated into the value of the security and may be recovered at any time simply by reselling the security at the inflated price."); *Robbins*, 116 F.3d at 1448 ("In fact, the claims presented to the jury do not attempt to link [the defendant's] misrepresentations to any decline in the value of plaintiffs' investment. Instead, plaintiffs simply claim they paid too much. But there is no evidence that this price inflation was removed from the market price of [the stock], causing plaintiffs a loss."). This allegation, and not an allegation that the material misrepresentation inflated the price, provides the required link between the falsity of the misrepresentation and an actual, recoverable loss. It also ensures that a plaintiff cannot seek windfall damages.

The logic behind this requirement is fundamental. The efficient market hypothesis presumes that a well developed, efficient market will incorporate all material information into the security's market price. *Basic*, 485 U.S. at 246. Just as the misrepresentation would inflate the market price at the time of purchase (not a recoverable loss), the correction of the misrepresentation would be reflected in the market price, thereby removing the artificial price inflation. At this point, the investor incurs a legally cognizable loss.

A plaintiff should not be permitted to exploit the fraud-on-the-market theory to presume a required element and then ignore its logical effect on another necessary element. A plaintiff cannot plead fraud on the market halfway. If plaintiffs are permitted to use the fraud-on-the-market theory to presume reliance at the pleading stage, then they must accept that theory when it comes to establishing loss causation.

C. The Ninth Circuit's Decision Precludes Meaningful Review of Loss Causation at the Pleading Stage.

The Ninth Circuit's decision would frustrate the Reform Act's goal of requiring the federal courts to scrutinize the sufficiency of a complaint at the motion to dismiss stage. Under that decision, a plaintiff in the Ninth Circuit need only recite a boilerplate phrase — that the misrepresentations artificially inflated the security's price at the time of purchase. There would be no way for the district court to test the sufficiency of such an allegation on a motion to dismiss. The litigation then would be permitted to proceed to protracted discovery and a battle of the experts on, among others, the issue of price inflation. Requiring only the mere recitation of a boilerplate phrase is a meaningless exercise that increases the risk that meritless complaints will proceed to discovery, rather than decreasing that risk as Congress intended.

Requiring a plaintiff to plead a corrective disclosure as well as a material misrepresentation, on the other hand, enables the district court to provide the type of meaningful review that the Reform Act requires. If plaintiffs must plead specific misrepresentations and a corrective disclosure, the court can test whether the requisite nexus is alleged between the fraud and the loss. Complaints that fail this pleading test would be dismissed, while complaints that allege the required nexus (assuming other elements are met) would proceed. This pleading requirement allows the courts to ful-

fill their role as gatekeepers on a motion to dismiss — as Congress envisioned under the Reform Act.

III. THE NINTH CIRCUIT'S DECISION WOULD INCREASE THE RISK THAT MERITLESS CLASS ACTIONS WOULD BE PERMITTED TO PROCEED, WITH HARMFUL CONSEQUENCES TO THE LIFE SCIENCES INDUSTRY.

When Congress passed the Reform Act, it made clear that biotechnology companies were particularly susceptible to securities fraud class action lawsuits.[52] This has proved to be the case for biotechnology companies and the life sciences industry as a whole. Securities fraud class actions filed against life sciences companies have increased both in number and as a percentage of overall securities fraud class actions. See *supra* Background Section C. And every one of these actions filed in 2003 and 2004 involved fraud-on-the-market claims. *Id.* Class action lawyers are taking advantage of the very nature of the scientific work performed by life sciences companies, which produces more unsuccessful projects than successful ones, to file class actions alleging that companies somehow misled the public in the past, and that the truth was only revealed with the bad news. How courts handle their role as gatekeepers to the discovery process, therefore, will substantially impact the life sciences industry.

First, the Reform Act's legislative history makes clear that Congress sought to stop the increase in the "cost of raising capital" that is caused by securities class actions.[53] It

[52] See S. Rep. No. 104-98, at 5 (stating that "high-tech, bio-tech and other growth companies . . . are sued disproportionately in 10b-5 litigation").

[53] *Id.* at 4, 14.

also made clear that requiring loss causation would play an important role in this effort.[54] The unremarkable, but important, premise underlying this conclusion is that unnecessary litigation expense depletes capital and increases its cost.[55]

The life sciences industry is one of the most capital intensive industries operating today. See *supra* Background Section D, 1. Allowing meritless claims to proceed beyond the pleadings stage would force life sciences companies to re-route existing capital from vital research and development projects to finance their defense and fund unwarranted settlements.

Second, Congress also intended the Reform Act to prevent "baseless and extortionate securities lawsuits" from deterring qualified individuals from accepting key positions at public companies.[56] If anything, though, this problem has recently been exacerbated in the life sciences industry. Class action lawyers are now suing the scientists, doctors, and researchers that manage the industry's vital research and development efforts. See *supra* Background Section D, 2. In all, nearly 20% of the securities class action complaints

[54] *Id.* at 8 (stating that "provisions intended to reduce the cost of raising capital . . . include . . . codifying the requirement under current law that plaintiffs prove that the loss in the value of their stock was caused by the Section 10(b) violation and not by other factors").

[55] Ralph K. Winter, *Paying Lawyers, Empowering Prosecutors, and Protecting Managers: Raising the Cost of Capital in America*, 42 DUKE L. J. 945, 948 (1993) ("Unnecessary civil . . . liability diminishes the return to, and increases the cost of, capital.").

[56] H.R. Conf. Rep. No. 104-369, at 31-32 (noting the "unwillingness of the best qualified persons to serve on boards of directors"); see also Winter, *supra*, at 945 ("The second effect of unnecessary civil and criminal liability is that participants in the capital markets, including the intermediaries and managers, may be deterred from engaging in efficient conduct by the fear of such liability.").

filed against life sciences companies in 2003 and 2004 named such individuals.

This is a direct attack on life sciences industry's most important asset: highly trained, uniquely qualified individuals. Life sciences companies are constantly struggling to find personnel with the technical skills, educational level and management experience necessary to conduct and manage the type of innovative and difficult research and development that the life sciences industry must conduct.[57]

Third, Congress also sought to deter the filing of abusive lawsuits against small developmental stage companies: "Smaller start-up companies bear the brunt of abusive securities fraud lawsuits. Many of these companies are high-technology companies which, inherently have unpredictable business prospects and, consequently, volatile stock prices."[58]

These types of companies are particularly important in the life sciences industry. Developmental stage biotechnology companies more and more are performing the important and innovative research and development in the industry. See *supra* Background Section A. Yet these smaller firms are also at the center of the litigation crisis. Almost half of the securities class actions filed against life sciences companies in 2003 were filed against companies with less than $500 million in market capitalization. And more than twenty percent of those suits were filed against companies with a

[57] See, *e.g.*, *Large Drug Mergers IMPACT Entire Pharmaceutical Chain*, N.J. Bus. Feb. 1, 2003, at 14 (noting that "the number of pharmaceutical jobs will increase by 14,000 by Feb. 1, 2003," but that "companies will have a hard time finding enough qualified people for those high-skilled jobs").

[58] S. Rep. No. 104-98, at 9.

market capitalization of less than $100 million. See *supra* Background Section C.

These small companies are especially vulnerable to the expense and disruption of extortionate securities class action litigation. Many generate little to no revenues, and their operations are singularly reliant on capital infusions. They are generally leanly staffed and focused on the development of one or two products. See *supra* Background Section A. Securities fraud lawsuits drain capital and increase its cost to these companies. The dismissal and deterrence of meritless securities fraud class actions is vital to allowing these companies to retain their focus on developing potentially important products, instead of defending meritless securities fraud class actions.

CONCLUSION

For the foregoing reasons, the judgment of the Ninth Circuit should be reversed.

Respectfully submitted.

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September 13, 2004